REMARKS

Claims 1, 3, 6-9, 11, 12, 16-20, 22-26, 28-31 and 33-70 are pending in the present application. Claims 56-70 were previously added. Claims 2, 4-5, 10, 13-15, 21, 27, and 32 were previously canceled. Claims 1, 3, 6-8, 30-31, and 33-55 are withdrawn from further consideration. Claims 9, 11, 12, 16-20, 22-26, 28, 29, and 56-70 are currently subject to examination. Claims 56 and 66-69 are canceled herein. Claims 9, 11, 12, 19, 28, and 57-65 are amended herein. Support for these amendments is found specifically in the original claims and at page 6, ¶ 0062 and page 7, ¶ 0068. New claims 71-73 have been added herein. Support for these claims is found in the original claims. Thus, it is believed that no new matter has been entered.

Rejections Withdrawn

The Examiner stated that the rejection of claims 12, 14, 16, 18, 19, 20, and 22-28 under 35 U.S.C. §102(a) as being anticipated by Reineke et al. (Molecular Therapy, (May 2004) Vol. 9, Supp. [1], pp. S139-S139. MA 362) and Liu et al. (J. Am. Chem. Soc. 126: 7422-7423, 2004) is withdrawn in view of the Declarations under 35 U.S.C. §1.132 indicating that the articles describe research conducted by Theresa M. Reineke and that the other authors completed assignments and carried out work under the direction and supervision of Dr. Reineke.

Additionally, the Examiner stated that the rejection of claims 12, 22, 25, 26, 56, 57, 59, and 70 under 35 U.S.C. §102(b) as being anticipated by Akelah et al. (Eur. Poly. J. 31(9): 903-909, 1995) is withdrawn in view of the amendment requiring that the agent is at least one nucleic acid molecule or at least one polypeptide or both.

Priority

The Examiner acknowledged Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. §119(e) or under 35 U.S.C. §§ 120, 121, or 365(c). However, the Examiner asserted that Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §119(e).

The Examiner did not find the Applicant's previously asserted arguments to be persuasive. Specifically, the Examiner asserted that it is unreasonable to conclude that the disclosure of the term "hairpin" in the context of oligonucleotides would immediately convey to one of ordinary skill in the art that at the time of invention that the Applicant wished to disclose

shRNA or any other specific hairpin RNA. Additionally, the Examiner asserted that the disclosure of preparing specific molecules by PCR amplification or restriction digestion does not convey that the Applicant intended to form complexes with PCR products generally. Moreover, the Examiner asserted that the disclosure provides no support for a peptide backbone which completely lacks a charge and that the disclosure does not account for the very specific structure that is a peptide nucleic acid backbone. Finally, the Examiner asserted that it is unclear to what pages Applicant intends to refer to in U.S. Provisional Application No. 60/531,999 in referencing pages 16, 17, and 21-23 as the specification is only 7 pages long.

Thus, the Examiner reasserted that the prior-filed applications fail to provide support for most of the species set forth in instant claims 19 and 28, e.g. mRNA, tmRNA, tRNA, rRNA, siRNA, shRNA, PNA, artificial chromosomes, cDNA, PCR products, restriction fragments, and ribozymes. Moreover, the Examiner asserted that because all claims under consideration embrace at least some of these species they do not have the benefit of support from the priority documents. Accordingly, the Examiner asserted that the effective date of the claims is 12/20/04.

Applicant respectfully traverses the Examiner's assertions.

Applicant reasserts that compliance with the written description requirement ***does not*** require an applicant to describe ***exactly*** the subject matter claimed; rather, the description must clearly allow a person of ordinary skill in the art to recognize that he or she invented what is claimed. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ 2d 1111, 1116 (Fed Cir. 1991) (emphasis added). The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.,* 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e. or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. *Eli Lilly*,

119, F.3d at 1568, 43 USPQ 2d at 1406. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. *See* MPEP § 2163. Moreover, description of a representative number of species ***does not*** require the description to be of such specificity that it would provide ***individual support*** for each species that the genus embraces. *See* MPEP § 2163 (emphasis added).

Based upon the legal standards regarding the written description requirement under 35 U.S.C. § 112, first paragraph, Applicant resubmits that the prior-filed applications provide adequate support of the claims of the instant application.

Firstly, Applicant submits that description of a representative number of species ***does not*** require the description to be of such specificity that it would provide ***individual support*** for each species that the genus embraces. Additionally, with regard to the Examiner's assertions that shRNA, PCR products, restriction fragments, and PNA do not have support in the Specification, Applicant submits that the written description requirement ***does not require*** an applicant ***to describe exactly*** the subject matter claimed. Thus, Applicant submits that the disclosures relating to shRNA, PCR products, restriction fragments, and PNA are adequate to meet the written description requirement.

Specifically, with regard to the disclosure relating to shRNA, Applicant submits that Application Nos. 60/531,399 and 60/574,131 disclose that the oligonucleotides may be DNA or ***RNAs***, (*see* pages 21-22, lines 14-21 & lines 1-6 & pages 21-22 ¶ 0046, emphasis added), ***and*** also disclose that the oligonucleotides may form ***hairpin structures*** such that a ***duplex binding site*** for a transcription factor is generated. (*See* Page 16, lines 5-8 & Page 17, ¶ 0035, emphasis added). Applicant submits that because the written description requirement ***does not require*** an ***exact description*** of the subject matter as claimed, these disclosures would allow a person of ordinary skill in the art to recognize shRNA as nucleic acids and/or agents as claimed.

Concerning the Examiner's assertion that the disclosure of preparing specific molecules by PCR amplification or restriction digestion does not convey that the Applicant intended to form complexes with PCR products generally, Applicant submits that Application Nos.

60/531,399 and 60/574,131 disclose that, "[r]egarding to a technology for producing the NF-κB decoy ***for use in the present invention***," (*see* page 22, lines 11-13 & page 22, ¶ 0047, emphasis added), and that Application No. 60/531,399 discloses, "[a] nontoxic polymeric delivery vector that delivers dsDNA decoys to inactivate NF-κB in myocardial cells, wherein the delivery vector is a polyamide formed by reacting a diamine co-monomer with a suitable carbohydrate." (*See* Page 7, lines 11-13). As the written description requirement ***does not require*** an ***exact description*** of the subject matter as claimed, Applicant submits that these disclosures would allow a person of ordinary skill in the art to recognize PCR products and restriction fragments as nucleic acids and/or agents as claimed.

Moreover, concerning the Examiner's assertion that the disclosure provides no support for a peptide backbone which completely lacks a charge and that the disclosure does not account for the very specific structure that is a peptide nucleic acid backbone, Application Nos. 60/531,399 and 60/574,131 disclose that the oligonucleotides may be DNA or RNAs and may contain modified nucleotides and/or pseudonucleotides and may be modified so to be less susceptible to biodegradation, such as those containing the thiophosphoric diester bond and those containing a methyl phosphate group ***containing no electric charge***. (*See* Pages 21-22, lines 14-21 & Pages 21-22, ¶ 0046, emphasis added). Applicant submits that because the written description requirement ***does not require*** an ***exact description*** of the subject matter as claimed, these disclosures would allow a person of ordinary skill in the art to recognize PNA as nucleic acids and/or agents as claimed.

Based upon these disclosures, Applicant submits that one of ordinary skill in the art would understand that Applicant wished to disclose shRNA, PCR products, restriction fragments, and PNA as nucleic acids and/or agents as claimed. Moreover, as the description of a representative number of species ***does not*** require the description to be of such specificity that it would provide ***individual support*** for each species in the genus and the Examiner does not dispute that the priority documents provide support for ssRNA, dsRNA, ssDNA, dsDNA, DNA, RNA hybrid molecules, plasmids, gene therapy constructs, and antisense constructs, Applicant further submits that the prior-filed applications disclose a representative number of the species. Accordingly, Applicant submits that the written description requirement for the claimed genus is satisfied and respectfully requests that the Examiner award the claimed invention a priority date of December 19, 2003, which corresponds to the filing date of Application No. 60/531,399.

Although Applicant maintains that one of ordinary skill in the art would understand that Applicant wished to disclose shRNA, PCR products, restriction fragments, and PNA as claimed and also maintains that the prior-filed applications disclose a representative number of the species, in order to expedite prosecution, dependent claims 11, 19, and 28 have been amended herein to delete the recitation of the species which the Examiner asserted the prior-filed applications fail to provide support. Specifically, dependent claims 11, 19, and 28 have been amended herein to recite, *inter alia*, the nucleic acid is selected from the group consisting of ssRNA, dsRNA, ssDNA, dsDNA, DNA, RNA hybrid molecules, plasmids, gene therapy constructs, antisense constructs, and combinations thereof.

Thus, for the above-stated reasons, Applicant respectfully requests that the Examiner award the claimed invention a priority date of December 19, 2003, which corresponds to the filing date of Application No. 60/531,399.

Finally, with regard to the Examiner's assertion that the Specification of U.S. Provisional Application No. 60/531,999 is only 7 pages long, Applicant submits that the Examiner made a typographical error of his reference of Application No. 60/531,999 and submits that the Examiner intended to refer to Application No. 60/531,399. Applicant further submits that the Specification of Application No. 60/531,399 is at least 39 pages in length. Moreover, Applicant submits that in referencing pages 16, 17, and 21-23 of U.S. Provisional Application No. 60/531,399, Applicant was referring to the portion of Application No. 60/531,399 with the header, "Patent 91830/521069" and was specifically referring to the page numbers indicated at the bottom left corner of each page of this portion.

New Claims

Claims 71-73 have been added herein to recite the species for which the Examiner asserts the prior-filed applications fail to provide support. Support for these claims is found in the original claims; thus, it is believed that no new matter has been entered. Specifically, dependent claims 71-73 have been added herein to recite, *inter alia*, the nucleic acid is selected from the group consisting of mRNA, tmRNA, tRNA, rRNA, siRNA, shRNA, PNA, artificial chromosomes, cDNA, PCR products, restriction fragments, ribozymes, and combinations thereof.

Drawings

The Examiner stated that the application as filed contains no drawings.

Claim Rejections - 35 U.S.C. §102

The Examiner rejected claims 9, 11, 12, 16-20, 22-29, and 56 under 35 U.S.C. §102(b) as being anticipated by Baker et al. (WO 01/87348).

Specifically, the Examiner asserted that the term "polyhydroxylamidoamine" is not a widely recognized term of art and that the specification fails to provide a limiting definition of the term. As a result, the Examiner gave the term the broadest reasonable interpretation, which the Examiner asserted includes molecules having several hydroxyl groups and at least one amidoamine group. The Examiner also asserted that Baker et al. teach polyamidoamine dendrimers modified with carbohydrate residues for improving dendrimer binding to target cells. Further, the Examiner asserted that each carbohydrate is considered to be a polyhydroxyl group and, as a result, Baker et al. teach polyhydroxylamidoamines. Finally, the Examiner asserted that these polyhydroxylamidoamines are also polyglycoamidoamines due to the inclusion of plural mannose residues.

Applicant respectfully traverses these assertions. However, to expedite prosecution, independent claims 9 and 12 have been amended herein to recite some of the limitations of claims 56 and 66-69. Specifically, independent claims 9 and 12 have been amended to recite specific poly(hydroxylamidoamine) compounds and the specific formulae associated with these compounds. For example, independent claims 9 and 12 have been amended to recite, *inter alia*, the poly(hydroxylamidoamine) comprises a poly(L-tartaramidoamine) depicted by the following structural formula, a poly(D-glucaramidoamine) depicted by the following structural formula, a poly(galactaramidoamine) depicted by the following structural formula, or a poly(D-mannaramidoamine) depicted by the following structural formula. Support for these amendments is found in the original claims and generally in the specification; thus it is believed that no new matter has been entered. Claims 56 and 66-69 have also been canceled herein to avoid redundancy. Additionally, claims 57-65 have been amended herein to provide proper antecedent basis; specifically, claims 57-65 have been amended herein to recite, "[t]he complex of claim 12."

As amended, Applicant submits that Baker et al. fail to disclose the limitations recited in amended independent claims 9 and 12. Thus, Applicant respectfully requests the withdrawal of the rejection of independent claims 9 and 12 under 35 U.S.C. § 102(b). Additionally, as claims 11, 16-20, and 22-29 depend from independent claims 9 and 12 and dependent claim 56 has been canceled herein, Applicant also respectfully requests the withdrawal of the rejection of these claims under 35 U.S.C. § 102(b).

Double Patenting

The Examiner provisionally rejected claims 9, 11, 12, 16-20, 22-26, 28, and 56-70 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 18 of co-pending Application No. 10/596,516.

The Examiner also provisionally rejected claims 9, 11, 12, 16-20, 22-26, 28, and 56-70 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 11-17 and 19-32 of co-pending Application No. 10/596,520.

The Examiner also provisionally rejected claims 9, 12, 16-20, 22-26, 28, 29, and 56 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-19 of co-pending Application No. 12/134,556.

Applicant maintains that the instant claims are patentably distinguishable over the references in combination or alone. However, in order to expedite prosecution and allowance, a terminal disclaimer has been filed with this Amendment along with payment of the appropriate fee in accordance with 37 C.F.R. §1.20(d) and a statement of common ownership. Accordingly, the double patenting rejection has been overcome and reconsideration is respectfully requested.

CONCLUSION

It is believed that the above represents a complete response to the Office Action dated August 17, 2010. In light of the foregoing, Applicant respectfully submits that the application is in condition for allowance. It is believed that no additional fees are required, but in the event this is incorrect, the Director is authorized to charge any fees which may be required in connection with the present Amendment, or credit any overpayment, to Deposit Account No. 04-1133. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to

discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,
DINSMORE & SHOHL LLP

By: /Hallie W. Wherley/
Hallie W. Wherley
Registration No. 66,800

Fifth Third Center
One South Main Street, Suite 1300
Dayton, Ohio 45402-2023
Telephone: (937) 449-6400
Facsimile: (937) 449-6405

HWW